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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/535,005	03/23/2000	William S. Bess	PD A0000259-03EJF	1060

7590 03/11/2004

FITZPATRICK, CELLA, HARPER & SCINTO
30 Rockefeller Plaza
New York, NY 10112-3801

EXAMINER

PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/535,005

Applicant(s)

BESS ET AL.

Examiner

Elli Peselev

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22, 25-29 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 5, 6, 8-13, 20 and 32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7, 14-19, 21, 22, 25-29, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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In view of applicant's amendment and further consideration, the Finality of the Office Action of February 6, 2004 is hereby withdrawn in order to introduce a new ground of rejection.

Claims 5, 6, 8-13, 20 and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

Claims 1-4, 7, 14-19 and 25-29 have been examined only insofar as the elected species is concerned.

Claims 1-4, 7, 14-19, 21, 22, 25-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (U.S. Patent No. 5,980,882) in combination with Ozaki et al (U.S. Patent No. 5,411,945) for the reasons set forth in the Office Action of November 22, 2002.

Applicant's arguments filed November 14, 2003 have been considered but have not been found persuasive.

Note that Ozaki et al teach that pullulan has film-forming ability and can be used in a variety of fields of formed products or moldings such as a granule, tablet, rod, film and sheet (column 1, lines 19-25). It is clear from the teaching by Ozaki et al that pullulan can be used in a solid form.

Claims 1-4, 7, 14-19, 21, 22, 25-29, 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (U.S. Patent No. 5,980,882) in combination with Leung et al (U.S. Patent No. 6,596,298).

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Eichman discloses a drug-resin complex but does not disclose an orally consumable film containing said complex. However, since an orally consumable film containing drugs was well known in the art at the time the instant invention was made as disclosed by Leung et al, a person having ordinary skill in the art at the time the instant invention was made would have been motivated to use the drug-resin complex disclosed by Eichman in combination with film disclosed by Leung et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 9.00-5.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev


ELLI PESELEV
PRIMARY EXAMINER
GROUP 1200